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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,777	12/29/2000	Hiroynki Morimoto	2500.6	3913
5514 7590 07/10/2008 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112				
EXAMINER				
TRAN, SUSAN T				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
07/10/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

09/647,777

Applicant(s)

MORIMOTO ET AL.

Examiner

S. Tran

Art Unit

1618

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-53, 63-70 and 72-102 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-53, 63-70 and 72-102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 42-53, 63-70 and 72-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al. EP 0 650 826 A1, in view of Tsushima et al. US 6,036,974 and Roche US 5,075,114.

Morimoto teaches a tablet compressing method using tableting machine with lubricant spraying mean (see abstract). The method comprising spraying lubricant uniformly on the surface of an upper punch, a lower punch, and a die, filling the die with pharmaceutical materials, and compressing the pharmaceutical material to form a drug tablet (columns 2-3 and columns 5-7).

Morimoto does not explicitly teach the claimed lubricant such as stearic acid.

Tsushima teaches a method for preparation of tablet comprises preparing the tableting material containing medicines and excipients, coating on the surface of the tableting material a lubricant, coating the surface of the punches with lubricant (columns 2 and 6). Lubricant includes stearic acid and stearic acid metal salt (column 6, lines 51-60). Thus, it would have been obvious to one of ordinary skill in the art to modify the tableting method of Morimoto using stearic acid as a lubricant in view of the teaching of Tsushima, because Tsushima teaches the use of stearic acid as a lubricant is known in pharmaceutical art, because Tsushima teaches using stearic acid as a lubricant to coat the surface of the die and punch, and because Morimoto teaches the desirability of using lubricant to coat the die and punch of the tableting machine.

Morimoto further does not teach the specific form of pharmaceutical material being claimed, such as, coated granule or granule in a matrix base. Nonetheless, Morimoto teaches that his tableting method can be used for tableting many kinds of tablets such as powdered or granular medicine, and so on (column 7, lines 34-38).

Roche teaches a medicament tablet comprising granules coated with polymers blend (see abstract and column 2, lines 45-60). The resulting coated granules were then compressed into tablet form using tableting machine having die wall and punches (columns 9-10). Thus, it would have been obvious for one of ordinary skill in the art to modify the pharmaceutical materials to be tabletted in Morimoto using the coated drug granule in view of the teaching of Roche, because the references teach the use of compressed tableting machine to compress pharmaceutical materials.

Response to Arguments

Applicant's arguments filed 04/07/08 have been fully considered but they are not persuasive.

At page 18 of the Remarks filed 04/04/08, applicant states that "sole remaining issue is the rejection of claims 42-53, 63-70 and 72-102 under 35 USC 103(a) being obvious over Tsushima US 6,036,974 and Roche US 5,075,114, optionally in view of Morimoto EP 0 650 826". To clear the record, there are two separate 103(a) rejections in the non final office action dated 10/05/07. The rejection over Morimoto is not optional.

Applicant's arguments with respect to the 103(a) rejection over Tsushima in view of Roche are persuasive, and therefore, this rejection has been withdrawn.

However, applicant did not make any argument with respect to Morimoto, therefore, the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1618